

REMARKS

In the Final Action dated August 29, 2008, claims 1, 2, 7, 10, 25, 28, 29, 37, 43, 44, 47-49, 53 and 54 are pending and under consideration. Claims 1 and 37 are allowed. Claims 44 and 49 are rejected under 35 U.S.C. §112, second paragraph, as indefinite. Claims 2, 10, 25, 28, 29, 43, 47-48, 53 and 54 are rejected under 35 U.S.C. §112, first paragraph, for allegedly introducing new matter and failing to comply with the written description requirement. Claims 7 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by NCBI Genbank EST Database Accession Number H57074.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance, or at least in a better condition for appeal. Therefore, entry of the Response is warranted and favorable consideration of all pending claims is respectfully requested.

35 U.S.C. §112, Second Paragraph

Claims 44 and 49 are rejected as indefinite. Both claims 44 and 49 depend from claim 1. The Examiner indicates that as a result of the previous amendment to claim 1, the nucleic acids recited in claims 44 and 49 are no longer encompassed by the genus of claim 1.

In response, Applicants have rewritten claims 44 and 49 as independent claims. The rejection is overcome in light of these amendments, and withdrawal thereof is respectfully requested.

35 U.S.C. §112, First Paragraph

Claims 2, 10, 25, 28, 29, 43, 47-48, 53 and 54 are alleged to contain new matter and therefore fail to comply with the written description requirement. Specifically, the Examiner

states that the recitation of "the derivative comprises amino acids 28-342 of SEQ ID NO: 4", which appears in claim 2, introduces new matter for two reasons: (i) The specification does not teach a derivative of an IL-13 receptor α -chain that *consists of* residues 28-342 of SEQ ID NO: 4; and (ii) The specification does not teach derivatives of an IL-13 receptor α -chain that *comprises* residues 28-342 of SEQ ID NO: 4.

The Examiner is of the opinion that the specification does not teach that a derivative consisting of residues 28-342 of SEQ ID NO: 4 (human) is part of the claimed invention. The Examiner goes on to state that the specification does not even teach that a derivative consisting of the corresponding residues (27-340) of the mouse sequence (SEQ ID NO: 2) is part of the claimed invention. While the Examiner acknowledges that the specification teaches that a recombinant IL-13 α -chain may be in soluble form, the Examiner contends that the specification does not teach any specific soluble form except a single example of a murine soluble form (amino acids 27-344 of SEQ ID NO: 2).

Further, the Examiner takes the position that the single example of a murine soluble form (amino acids 27-344 of SEQ ID NO: 2) may provide support for a derivative consisting of the exact corresponding residues of the human sequence (Thr28-Thr346); however, it does not provide support for either a slightly shorter form of the murine (residues 27-340 of SEQ ID NO: 2) or the corresponding human (28-342 of SEQ ID NO: 4) sequences. According to the Examiner, there is nothing in the specification directing the skilled artisan to these slightly shorter sequences; and further, the specification does not contain any teachings indicating that a derivative consisting of the specific residues corresponding to the isolated extracellular domain of either protein is part of the invention.

Applicants respectfully submit that the written description requirement does not require *literal* recitation of the claimed subject matter in the specification. The proper legal standard concerning the written description requirement is whether the specification as originally filed conveys to those skilled in the art with reasonable clarity that the inventors had possession of the claimed invention at the time of filing. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). In the present case, Example 6 on page 37 of the specification explicitly states that "the extracellular region of the protein contained an immunoglobulin like domain (amino acids 27-117), in addition to a typical haemopoietin receptor domain (amino acids 118-340)" (emphasis added). Further, as the Examiner has admitted, the specification clearly conveys to those skilled in the art that a soluble form of the IL-13R is part of the claimed invention. The Examiner has also noted himself that those in the art understand a soluble receptor to mean a receptor that has been rendered soluble by e.g., deleting all or a part of the transmembrane domain. In light of this common knowledge of those skilled in the art about a soluble receptor, and considering the entirety of the teaching in the specification, especially the specific reference to soluble forms and to the extracellular region of murine IL-13 receptor, those skilled in the art would have understood that a receptor that consists of the extracellular region (amino acids 27-340 of SEQ ID NO: 2) of murine IL-13R is part of the claimed invention. Those skilled in the art would then naturally deduce the human counterpart, i.e., amino acids 28-342 of SEQ ID NO: 4, as part of the claimed invention, based on the sequence alignment provided in Figure 7.

Moreover, Applicants respectfully submit that those skilled in the art would have understood from the specification that the invention would encompass soluble forms that contain additional amino acids beyond the extracellular domain. Again, as the Examiner has noted in the

Action, those in the art understand a soluble receptor to mean a receptor that has been rendered soluble by e.g., deleting *all or a part* of the transmembrane domain. Further, in the previous Action dated July 25, 2008, the Examiner agreed that variants that comprise the entire unaltered extracellular domain of human IL-13 α would probably retain binding to IL-13. In fact, as demonstrated in the present application, a soluble murine form (amino acids 27-344 of SEQ ID NO: 2), which includes four amino acids from the transmembrane segment in addition to the entire extracellular domain (amino acids 27-340), did bind to IL-13 (see page 40 of the specification).

Although Applicants disagree with the Examiner's reasoning, solely in an effort to advance prosecution, Applicants have amended claim 2 to revert to the recitation used previously, "wherein the derivative is an extracellular domain of the IL-13 receptor α -chain which comprises amino acids 28-346 of SEQ ID NO: 4". In addition, claims 43 and 48 have also amended to revert to the previous versions of amino acid and nucleotide positions. It is believed that the claims, as presently amended, are fully supported by the specification and do not introduce new matter.

In view of the foregoing, the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. §102(b)

Claims 7 and 25 are rejected under 35 U.S.C. §102(b) as allegedly anticipated NCBI Genbank EST Database Accession Number H57074. EST H57074 is a 154 nucleotide sequence that allegedly has 98.1% similarity to residues 469-623 of SEQ ID NO: 3, and would therefore hybridize to the complement of SEQ ID NO: 3, according to the Examiner.

The asserted EST has the following sequence:

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aacctgagct acatgaagtg ttcttggctc cctggaagaa taccagtccc  
gacactaact atactctcta ctattggcac agaagcctgg naaaaattca  
tcaatgtgaa aacatcttta gagaaggcca atactttggt tgttccttg  
atct
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Translation of this EST provides the following 51 amino acid peptide:

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1 NLSYMKCSWL PGRIPVPTLT ILSTIGTEAW XKFINVKTSL EKANTLVVPL I 51
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Alignment with the relevant portion of IL-13R α of SEQ ID NO: 4 shows that while the first 13 amino acids are identical, only 2 of the remaining 38 amino acids are identical.

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1 NLSYMKCSWL PGRIPVPTLT ILSTIGTEAW XKFINVKTSL EKANTLVVPL I 51  
137 NLSYMKCSWL PGRNTSEDTN YTLYYWHRS L EKIHCENIF REGQYFGCSF D 187
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Given its short length and low level of identity, Applicants respectfully submit that it is unlikely that this EST sequence would encode an IL-13R α -chain that binds IL-13, as presently claimed. Therefore, Applicants respectfully submit that EST H57074 does not meet each and every element of the claimed invention. Accordingly, the rejection under 35 U.S.C. §102(b) is overcome, and withdrawal thereof is requested.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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